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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,300	04/09/2001	Hans R. Brunner	SSM-487US	2492

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EXAMINER
OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 12/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,300	BRUNNER ET AL.	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2001 and 13 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Preliminary Amendments

1. Preliminary amendments filed 4/9/01 and 11/13/02 were entered into the record.

Claims 1-18 are pending in this application. Of these claims, 1, 13 and 14 are independent.

Drawings

2. The specification indicates the application includes 5 figures, but the Examiner is unable to find any figures in the application.

The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing.

Claim Objections

3. Claims 1-18 are objected to because of the following informalities:

Claims 1, 13 and 14 contain the abbreviation "cm"; replacement with --centimeters-- is suggested.

Claims 10, 11, 17 and 18 contain the abbreviation "min."; replacement with --minutes-- is suggested.

A period is missing from the end of claims 10, 11, 17 and 18.

Appropriate correction is required.

4. The reference numeral character "(B)" in claim 13 is superfluous and should be deleted.

Abstract

5. The abstract of the disclosure is objected to because of the phrase "The invention relates to". It is also suggested that "cm" be replaced with --centimeters--.

The Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 8, 9, 13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, "the pressure" lacks antecedent basis.

In claims 4 and 9, the word "overpressure" leads to confusion as "overpressure" is

normally associated with a situation where a pressure relief device is used to remove pressure and avoid an accident because, given the construction, a device is pressurized beyond a safe level.

Claims 8 and 16 are indefinite because of the phrase "amplitude and/or repetition frequency".

Claim 9 is unclear because the measuring of pressure lacks antecedent basis and the structure to enable the measuring of the pressure is not claimed.

Claim 13 is unclear because "assisting the return" does not define what is being returned. The phrase --assisting the return of body fluids-- is suggested.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 9-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Gardner et al. (US 5634889). Gardner et al. disclose a medical appliance for intermittently pulsed compression of proximal joint and adjacent tissue of the human body.

As related to claim 1, the readily portable medical appliance for intermittent compression of human extremities, includes a cuff (14) with a single chamber (15) and a miniature pressure generator (21) (figure 1 and 1A; c 1, ll 35-46; c 3, ll 2-12 and 53-56). The width of the cuff in the direction of return is sized to be a rectangular or trapezoidal shape with lateral edges that

converge producing lapped engagement to enclose a knee or elbow. A cuff that would converge as described to encircle a knee or elebow would be at most 25 centimeters (figures 1, 1A and 4; c 4, ll 12-36).

As related to claim 2, since the cuff is pressurized to a peak pressure of 75 mm Hg, the cuff inherently corresponds to a cuff used for blood pressure measurements, as blood pressure cuffs operate at about 60 mm Hg. (See cited references)

As related to claim 7, the controller actuates a pressure generator (21) to pressurize the cuff with a defined pressure amplitude and a defined repetition frequency (c 3, l 53 – c 4, l 8).

As related to claim 8, selective control of the pump enables the peak pressure, read as amplitude and the intervals between successive pulses, read as the repetition frequency to be varied (c 3, l 66 – c 4, l 8).

As related to claim 9, the chamber of the cuff is filled to a peak pressure of 75 mm Hg, read as the point of overpressure (c 3, ll 56-61).

As related to claim 10, the chamber is filled at least every 20 seconds or three times a minute (c 3, l 66 - c 4, l 5).

As related to claim 11, the chamber is filled at least every 20 seconds or 15 times in five minutes (c 3, l 66 - c 4, l 5).

As related to claim 12, the cuff and pump can be uncoupled when the inlet 19 is disconnected from the pump and associated conduit (figure 1 and 1A and c 3, ll 53-53).

As related to claim 13, the readily portable medical appliance for stimulating flow of body fluids, includes a cuff (14) with a single chamber (15) and a miniature pressure generator (21) (figure 1 and 1A; c 1, ll 35-46; c 3, ll 2-12 and 53-56). The width of the cuff in the direction

of return is sized to be a rectangular or trapezoidal shape with lateral edges that converge producing lapped engagement to enclose a knee or elbow. A cuff that would converge as described to encircle a knee or elbow would be at most 25 centimeters (figures 1, 1A and 4; c 4, ll 12-36).

As related to claim 14, the method to use the readily portable medical appliance for stimulating the flow of body fluid, includes applying a cuff (14) with a single chamber (15) to an extremity and intermittently pressurizing the cuff using a miniature pressure generator (21) (figure 1 and 1A; c 1, ll 35-46; c 3, ll 2-12 and 53-56). The width of the cuff in the direction of return is sized to be a rectangular or trapezoidal shape with lateral edges that converge producing lapped engagement to enclose a knee or elbow. A cuff that would converge as described to encircle a knee or elbow would be at most 25 centimeters (figures 1, 1A and 4; c 4, ll 12-36).

As related to claim 15, the controller actuates a pressure generator (21) to pressurize the cuff with a defined pressure amplitude and a defined repetition frequency (c 3, l 53 – c 4, l 8).

As related to claim 16, selective control of the pump enables the peak pressure, read as amplitude and the intervals between successive pulses, read as the repetition frequency to be varied (c 3, l 66 – c 4, l 8).

As related to claim 17, the chamber is filled at least every 20 seconds or three times a minute (c 3, l 66 - c 4, l 5).

As related to claim 18, the chamber is filled at least every 20 seconds or 15 times in five minutes (c 3, l 66 - c 4, l 5).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint Inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. The Applicant is advised of the obligation under 37 CFR 1.56 to point out the Inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gardner et al. (US 5634889) in view of Raines et al. (US 6152881). As discussed in paragraph 7 of this action, Gardner et al. disclose the claimed invention except for the pressure generator being a roller pump.

Raines et al. disclose a method to characterize blood flow using a blood pressure cuff and teach that it is known to pressurize the cuff using a positive displacement pump (101) (figure 4 and c 15, ll 1-6). A roller pump is a type of positive displacement pump. Absent any teaching of criticality or unexpected results for the specific type of pump used, substitution of a positive displacement pump for a roller pump would have been an obvious design choice. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was

made to modify the medical appliance as taught by Gardner et al., with the roller pump, as taught by Raines et al. to specify a type of pump known in the art that effectively pressurizes a blood pressure cuff.

10. This rejection reflects the Examiner's best understanding of the invention, given that no figures or drawings were found in the application. Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardner et al. (US 5634889) in view of Harada et al. (US 4928701). As discussed in paragraph 7 of this action, Gardner et al. disclose the claimed invention except for:

- a pressure control means to connect the cuff to the atmosphere when the cuff is overpressured (claim 4),
- the pressure control means comprising an outlet valve / overpressure outlet forming an overpressure outlet (claim 5),
- the pressure control means comprising a restrictor in a conduit and a stopper as a function of the pressure in the inlet and outlet of the restrictor (claim 6), and
- a controller which switches the generator ON/OFF to pressurize the cuff (claim 7).

Harada et al. disclose a method and apparatus for monitoring blood pressure and teach that it is known to provide a controller that switches the generator ON/OFF to pressurize the cuff and to provide a pressure control means that contains an outlet valve / overpressure outlet, a restrictor in a conduit, and a stopper so the cuff is connected to the atmosphere when the cuff is overpressured. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical appliance as taught by Gardner et al., with the following elements as taught by Harada et al.:

- a central processing unit (24), read as a component of the pressure control means, to connect the cuff (10) to the atmosphere when the cuff (10) is overpressured, read as when the pressure exceeds the peak pressure or the time period for inflation is exceeded (claim 4) to enable the pressure in the cuff to be rapid removed from the cuff preventing harm to the patient, (figure 1; c 6, ll 7-10 and 16-25),
- an additional pressure control means component, a rapid deflation port (16b), read as the outlet valve / overpressure outlet (claim 5), to enable the pressure in the cuff to be rapid removed from the cuff preventing harm to the patient, (figure 1 and c 6, ll 7-10),
- further pressure control means components: a directional control valve (16), read as the restrictor, in a conduit (19) and the position selector in the control valve (16), read as a stopper (claim 6) to enable the selection by the controller to inflate or deflate the cuff (c 5, l 57 – c 6, l 10; c 6, ll 1 16-25) and
- a controller (24) which switches the generator ON/OFF to pressurize the cuff (claim 7) to enable the cuff to be inflated and deflated (c 6, ll 16-25) .

Other Prior Art Cited

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 3552381 to Burns teaches blood pressure cuffs operate at 60 mm Hg. (c 3, ll 71-75)

US 4862895 to Yamasawa et al. teach a roller pump can be used to pressurize a blood pressure cuff. (c 1, ll 54-61)

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
12/9/02

JEFFREY R. JASTRZAB
PRIMARY EXAMINER
12/11/02